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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,564	10/16/2001	Avi J. Ashkenazi	GNE.2630P1C25	5282

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EXAMINER	
ANGELL, JON E	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/978,564	ASHKENAZI ET AL.	
	Examiner	Art Unit	
	Jon Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/25/02; 6/9/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendments filed 10/16/2001 and 03/25/2002 are acknowledged. The amendments have been entered. The specification has been amended as indicated. Claims 1-57 have been cancelled. Claims 58-63 are currently pending in the application and are addressed herein.

Title and Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. For example, see page 124, line 37 and page 127, line 18. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. Applicant is required to delete ALL embedded hyperlinks and/or other forms of browser-executable code. See MPEP § 608.01.

The disclosure is objected to because of the following informalities: the address disclosed for ATCC (e.g., see page 374, lines 34-35) is incorrect, ATCC is now located in Manassas, VA. Additionally, the status of the prior US application 09/918,585 (now abandoned) should be updated (e.g., see preliminary amendment filed 3/25/2002).

Appropriate correction is required.

Biological Deposits

A statement in the specification indicating that the biological deposit ATCC 209616 has been deposited under the provisions of the Budapest Treaty can be found in the specification (see under "Deposit of Material" on page 372 through page 375 of the specification. The statement indicates that under the provisions of the Budapest Treaty, a viable culture of the deposit will be maintained for 30 years form the date of deposit, and that the deposit will be made available by ATCC under the terms of the Budapest Treaty, and subject to an agreement between Genentech, Inc. and ATCC, which assures permanent and unrestricted availability of the progeny of the culture of the deposit to the public upon issuance of the pertinent U.S. patent or upon laying open to the public of any U.S. or foreign patent application, whichever comes first, and assures availability of the progeny to one determined by the U.S. Commissioner of Patents and Trademarks to be entitled thereto according to 35 USC 122 and the Commissioner's rules pursuant thereto (including 37 CFR 1.14 with particular reference to 886 OG 638).

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 3/25/2002 and 6/9/2003 are acknowledged. With respect to the IDS submitted 6/9/2003, the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. With respect to the IDS submitted 3/25/2002, the database search results have not been considered because the information on the referred databases is incomplete. In order for the databases referred to be considered, Applicants are required to provide complete information, including such database name, accession number, and publication date.

Specific and Substantial Asserted Utility

It is noted that the instant claims are drawn to an antibody that binds to the polypeptide of SEQ ID NO: 59 (the PRO363 polypeptide). The specification discloses that the PRO363 polypeptide was tested in a number of different assays and was found to test positive in, among others, Assay 10: chondrocyte re-differentiation assay (e.g., see Example 126, page 351). The results of the Assay 10 are sufficient to demonstrate a specific and substantial utility for the PRO363 polypeptide. As such, the claimed antibody that binds to the PRO363 polypeptide is also deemed to have a specific and substantial utility.

Priority

According to the priority statement of 03/25/2002, the claimed subject matter defined in the instant application is supported by parent application serial nos. 09/918585, PCT/US00/04341, 09/380138, PCT/US99/05028, and 60/078910. Based on the information given by applicant and an inspection of the patent applications, the examiner has concluded that the subject matter defined in this application is supported by the disclosure in application serial no. PCT/US00/04341, filed 18 February 2000, but is not supported by any of the earlier applications because no utility for the claimed antibody, is disclosed in the earlier applications. The results of the chondrocyte redifferentiation assay are first reported in PCT/US00/04341. Under 35 U.S.C. 120, a claim in a U.S. application is entitled to the benefit of the filing date of an earlier filed U.S. application if the subject matter of the claim is disclosed in the manner provided by 35 U.S.C. 112, first paragraph, in the earlier filed application. See MPEP 201.11.

Since the applications prior to PCT/US00/04341 do not disclose a specific and substantial utility for the antibody that binds to the PRO363 polypeptide, said applications are not enabling.

Accordingly, the subject matter defined in claims 58-63 have an effective filing date of February 18, 2000.

Should the Applicant disagree with the examiner's factual determination above, it is incumbent upon the applicant to provide the serial number and specific page numbers of any parent application filed prior to February 18, 2000 that specifically supports the particular claim limitations for all the pending claims which applicant considers to have been in possession of and fully enabled prior to February 18, 2000.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 58-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0055139 A1 (**HOLTZMAN** et al., published May 9, 2002 with priority to 09/312359, filed May 14, 1999).

HOLTZMAN teaches a polypeptide (human A236 protein) that is 100% identical to SEQ ID NO: 59 (see attached; also see paragraph [0129] describing Figure 23, SEQ ID NO: 23 and SEQ ID NO: 24). HOLTZMAN indicates that antibody substances that specifically bind to the A236 polypeptide can be made, and explicitly indicates that monoclonal antibodies, polyclonal antibodies, antibody fragments, single-chain antibodies, and humanized antibodies can be made (see paragraphs [0098], [0617], and [0629]). HOLTZMAN also teaches that the antibodies can be modified such that they are labeled with a detectable substance such as a radioactive material or fluorescent material (e.g., see paragraph [0620]).

HOLTZMAN does not indicate that the antibodies have actually been reduced to practice.

However, making monoclonal or polyclonal antibodies, antibody fragments, single-chain antibodies, humanized antibodies and labeled antibodies was conventional and routine in the art. Furthermore, HOLZTMAN refers to several specific references for guidance on making the antibodies (e.g., see paragraphs [0617], [0618], [0620] and [0624])

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make antibodies that specifically bind to human A236 protein (which is 100% identical to the instant SEQ ID NO: 59) including monoclonal antibodies, antibody fragments, single-chain antibodies, humanized antibodies and labeled antibodies that specifically bind to instant SEQ ID NO: 59 with a reasonable expectation of success.

The motivation to combine the references to create claimed invention is provided by HOLTZMAN who teaches that monoclonal or polyclonal antibodies, antibody fragments, single-chain antibodies, humanized antibodies and labeled antibodies are useful as research tools such as isolating or detecting the target protein or as therapeutic molecules for treating human subjects (e.g., see paragraphs [0618] and [0620]).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon Eric Angell, Ph.D.
Art unit 1635